PEC Innovation 4 (2024) 100256

Contents lists available at ScienceDirect

PEC Innovation

journal homepage: www.elsevier.com/locate/pecinn

Digital health outreach to promote postpartum screening after gestational diabetes: A randomized factorial pilot study

Susan D. Brown [a,b,*], Brittany L. Garcia [a], Jenna L. Ritchie [b], Ai-Lin Tsai [b], Andrea Millman [b], Mara Greenberg [c], Charles P. Quesenberry [b], Assiamira Ferrara [b]

[a] Department of Internal Medicine, University of California, Davis, Sacramento, CA, USA
[b] Division of Research, Kaiser Permanente Northern California, Oakland, CA, USA
[c] Regional Perinatal Service Center, Kaiser Permanente Northern California, Oakland, CA, USA

ARTICLE INFO

Keywords:
Gestational diabetes mellitus
Postpartum
Screening
Diabetes prevention
Patient engagement
Outreach
Multiphase Optimization Strategy

ABSTRACT

Objective: We examined the acceptability and feasibility of a multi-component digital health outreach intervention to promote uptake of guideline-recommended postpartum screening for type 2 diabetes among patients with gestational diabetes (GDM).

Methods: We conducted a 2^4 randomized factorial experiment as part of the Multiphase Optimization Strategy (MOST) preparation phase for developing behavioral interventions. Participants with current or recent GDM in an integrated healthcare system were randomized to receive an outreach message with up to four intervention components, designed to be self-administered in about 10 min and efficiently delivered online via REDCap: a streamlined values affirmation, personalized information on diabetes risk, an interactive motivational interviewing-based component, and an interactive action planning component. Patient-reported acceptability and feasibility outcomes were assessed via survey.

Results: Among 162 participants, 72% self-identified with a racial/ethnic minority group. Across components, acceptability scores averaged 3.9/5; ≥91% of participants read most or all of the outreach message; ≥89% perceived the amount of information as "about right"; and ≥ 87% completed ≥1 interactive prompt.

Conclusion: Each intervention component was acceptable to diverse patients and feasible to deliver in a brief, self-directed, online format.

Innovation: These novel components target unaddressed barriers to patient engagement in guideline-recommended postpartum diabetes screening and adapt theory-based behavior change techniques for large-scale use.

1. Introduction

Gestational diabetes (GDM) is a common pregnancy complication, found to affect up to 14% of pregnancies [1,2], which increases risk for type 2 diabetes after delivery [3]. Clinical guidelines urge individuals with GDM to complete an oral glucose tolerance test (OGTT) to screen for diabetes within 4–12 weeks after delivery [4-6]. If results from the OGTT indicate prediabetes and the individual has an elevated body mass index, only 5 must receive an evidence-based intervention to prevent 1 case of diabetes over 3 years [7]. Yet despite this clear pathway to diabetes prevention, rates of guideline-recommended postpartum diabetes screening remain suboptimal and uneven across racial/ethnic groups [8,9], delaying early treatment and prevention. Nationally, only 7% of insured individuals with GDM obtain the recommended OGTT by 12 weeks postpartum, and Black individuals with GDM are least likely to obtain a recommended test [9]—despite 52% higher risk for developing diabetes as compared to White individuals [10]. Prior studies have identified multiple patient-level barriers to postpartum screening including fear of abnormal results, low perceived risk for developing type 2 diabetes after GDM, competing priorities, and logistical barriers and time constraints [11,12].

Few interventions to increase uptake of postpartum diabetes screening have been tested in randomized controlled trials. Existing trials have focused on health system operational strategies, such as reminders [13-15]. Observational reports of operational strategies have also included centralized bulk ordering of OGTTs as part of population

* Corresponding author at: University of California, Davis, 4150 V Street, Suite 2400, Sacramento, CA 95817, USA.
E-mail address: sdmbrown@ucdavis.edu (S.D. Brown).

https://doi.org/10.1016/j.pecinn.2024.100256
Received 23 March 2023; Received in revised form 18 December 2023; Accepted 17 January 2024
Available online 19 January 2024

health management [16]. Such operational strategies have been linked with a 33% increase in screening [16] and reduced incidence of severe diabetes [17]. In contrast, interventions targeting patient-level factors—including motivation to engage in preventive care during the demanding postpartum period—remain lacking. Interventions that are theory-driven, acceptable to diverse patients, and feasible to deliver at-scale in health system settings are vitally needed to advance implementation of guideline-recommended postpartum care and improve maternal cardiometabolic health.

1.1. Objectives

We applied the Multiphase Optimization Strategy (MOST) [18] to pilot components of a digital health outreach intervention designed to promote guideline-recommended postpartum diabetes screening following GDM by targeting patient-level barriers. As part of Phase 1 (Preparation) within the MOST framework, the objectives of this randomized factorial pilot study were to (i) determine whether each intervention component is acceptable and feasible among diverse patients with GDM; and (ii) determine the feasibility of study procedures. If successful, this vital phase of MOST lays the foundation for a future randomized trial as part of Phase 2 (Optimization).

2. Methods

2.1. Participants

Our target population consisted of all pregnant or postpartum individuals with GDM who had not yet completed recommended postpartum screening in Kaiser Permanente Northern California (KPNC), a large integrated healthcare delivery system. The sample included individuals across the perinatal period to prepare for potential implementation of the intervention during pregnancy or postpartum. Eligibility criteria, primarily assessed via the electronic health record (EHR), included age $\geq$ 18 years old; being pregnant at $\leq$38 weeks' gestation or being 12–52 weeks postpartum; having a diagnosis of GDM in the current or most recent pregnancy; no laboratory record of completing the recommended 2-h, 75-g OGTT; and no evidence of having diabetes outside of pregnancy (the latter two criteria again confirmed via self-report).

2.2. Design and procedure

Eligible participants were identified in the EHR and contacted once by email (or postal letter, for those with no available email address). There was no other interaction with research staff. Recruitment materials described the nature of the study, the risks and benefits of participation, and a link to the baseline survey, with consent indicated through completion of the survey. Participants were offered compensation for their time with a $25 gift card. Recruitment was conducted from November–December 2019.

Using a 2^4 full factorial design, participants were randomized to view an online outreach message containing up to 4 intervention components to promote postpartum diabetes screening. Allocation to 16 experimental conditions was stratified by pregnancy status (pregnant vs. postpartum). Investigators and the statistical analyst were blinded to randomized assignment. The analyst generated the allocation sequence; research staff assigned and enrolled participants. The study was approved by the Kaiser Permanente Northern California institutional review board (protocol number 1426728).

Participants were invited to complete a single survey, starting with baseline items to assess demographic characteristics (Table 1). The baseline survey included items from the validated American Diabetes Association (ADA) Type 2 Diabetes Risk Test [19,20] to assess risk for type 2 diabetes (e.g., family history of diabetes); these risk factors were used to automatically populate the personalized risk information for participants randomized to that component (described below). Baseline survey items also assessed perceived benefits and barriers, perceived norms, and recall of clinician advice about postpartum screening using measures adapted for this study from prior research; [21-26] baseline results are reported elsewhere [12].

Immediately after the baseline survey items, participants were presented with the outreach message in their assigned condition. This appeared in a new section entitled “Your opinions about health information,” with the following instructions: “Next you'll see health information that a [health system] member like you might receive from her provider…Afterwards, we'll ask for your honest feedback about it.” Immediately after exposure to the intervention, participants completed follow-up survey items to assess acceptability and feasibility outcomes. Study implementation, including survey administration and intervention, was carried out using REDcap [27]. Given the 16 experimental conditions with 2 strata (Table 2), 32 REDcap instruments were required, each pre-tested by research staff to ensure they contained the appropriate intervention components. Data collection was completed in 2020.

2.3. Intervention

The intervention was designed to target patient-level barriers to receiving postpartum screening after GDM, leveraging behavior change theory, our prior empirical research, and collaboration with health system leaders, who contributed as key stakeholders offering input during intervention development.

Aligned with standard care in KPNC, the online outreach message included standard health information across all experimental conditions about postpartum screening and diabetes prevention after GDM. This

Table 1
Characteristics of participants, by intervention component and overall ($N = 162$).

	(1) Values Affirmation		(2) Personalized Risk Information		(3) Motivational Interviewing-based		(4) Action Planning		Overall
	ON	OFF	ON	OFF	ON	OFF	ON	OFF	
Age, Mean (SD)	33.4 (5.1)	32.7 (4.8)	33.2 (5.0)	32.9 (4.9)	33.5 (4.8)	32.7 (5.1)	33.1 (5.0)	32.9 (4.9)	33.0 (4.9)
Race/Ethnicity, % (n)									
African American	7.3 (6)	10.0 (8)	4.9 (4)	12.5 (10)	13.0 (9)	5.4 (5)	5.9 (5)	11.7 (9)	8.6 (14)
Asian or Pacific Islander	32.9 (27)	30.0 (24)	39.0 (32)	23.8 (19)	33.3 (23)	30.1 (28)	32.9 (28)	29.9 (23)	31.5 (51)
Hispanic	23.2 (19)	15.0 (12)	14.6 (12)	23.8 (19)	18.8 (13)	19.4 (18)	20.0 (17)	18.2 (14)	19.1 (31)
Multi-racial/ethnic	14.6 (12)	10.0 (8)	14.6 (12)	10.0 (8)	10.1 (7)	14.0 (13)	10.6 (9)	14.3 (11)	12.3 (20)
White	22.0 (18)	33.8 (27)	26.8 (22)	28.8 (23)	24.6 (17)	30.1 (28)	30.6 (26)	24.7 (19)	27.8 (45)
Other	0 (0)	1.3 (1)	0 (0)	1.3 (1)	0 (0)	1.1 (1)	0 (0)	1.3 (1)	0.6 (1)
Education, % (n)									
High school or less	11.0 (9)	17.5 (14)	11.0 (9)	17.5 (14)	18.8 (13)	10.8 (10)	14.1 (12)	14.3 (11)	14.2 (23)
At least some college	89.0 (73)	82.5 (66)	89.0 (73)	82.5 (66)	81.2 (56)	89.2 (83)	85.9 (73)	85.7 (66)	85.8 (139)
Pregnancy Status, % (n)									
Pregnant	39.0 (32)	43.8 (35)	42.7 (35)	40.0 (32)	40.6 (28)	41.9 (39)	45.9 (39)	36.4 (28)	41.4 (67)
Postpartum	61.0 (50)	56.3 (45)	57.3 (47)	60.0 (48)	59.4 (41)	58.1 (54)	54.1 (46)	63.6 (49)	58.6 (95)

Table 2
Experimental conditions in the 2^4 randomized factorial pilot study.

Conditions	(1) Values Affirmation	(2) Personalized Risk Information	(3) Motivational Interviewing	(4) Action Planning
1	Off	Off	Off	Off
2	Off	Off	Off	On
3	Off	Off	On	Off
4	Off	Off	On	On
5	Off	On	Off	Off
6	Off	On	Off	On
7	Off	On	On	Off
8	Off	On	On	On
9	On	Off	Off	Off
10	On	Off	Off	On
11	On	Off	On	Off
12	On	Off	On	On
13	On	On	Off	Off
14	On	On	Off	On
15	On	On	On	Off
16	On	On	On	On

included the rationale for screening; information on type 2 diabetes risk after GDM; a step-by-step description of the screening procedure; that screening may be available at no cost to patients (covered under insurance as standard preventive care); and where to find more information (a link to patient education from the National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases). Consistent with evidence on the sender's importance for health communication [28,29], the concluding salutation was "signed" by the health system clinical leader (MG, physician and co-author) who is responsible for GDM clinical care in KPNC (including name, photo, and affiliation).

All materials were written at less than a 6th grade reading level and took an estimated 10 min to complete for each experimental condition. Aligned with the NIH Behavior Change Consortium framework [30,31], we conceptualized intervention fidelity as including the intervention *design* (e.g., the dose is standardized; the theoretical bases of the intervention are specified); intervention *receipt* (e.g., the proportion of participants who attend to their assigned message); and intervention *enactment* (e.g., the proportion who engage in interactive modules). For the purpose of this pilot study, intervention receipt and enactment comprised our feasibility outcomes, further described below.

The outreach message contained up to four intervention components, as described below and summarized in Table 3. The four components target barriers identified in the literature and our prior research including psychological threat, risk perception, ambivalence and competing priorities, and the logistical and practical barriers to screening [12]. The order of components was fixed, appearing in the following order if combined. For example, the Values Affirmation appeared first as it is designed to shape reactions to health information that follows it.

2.3.1. Component 1: values affirmation

Self-affirmation theory posits that people are naturally inclined to avoid or dismiss health information that threatens a self-perception of adequacy [32]. For example, the psychological threat raised by the prospect of a new diagnosis or being at-risk for disease could discourage patients from engaging with preventive health information. Values affirmation strategies—typically writing a narrative about one's personal strengths or values, such as religion or relationships [33]—broaden the view of the self and its psychological resources beyond the threatening domain, thereby increasing one's ability to respond adaptively (self-integrity). In so doing, threatening health messages evoke less defensiveness [33]. A values affirmation can thus be designed to reduce the psychological threat associated with the prospect of being diagnosed with a chronic disease. Meta-analyses show it improves acceptance of health information, intentions for health behaviors, and behaviors themselves, especially among racially and ethnically diverse samples [34-36]. Participants allocated to receive this component were presented with a two-sentence values affirmation, prompting

Table 3
Summary of intervention components.

Component	Description	Excerpt	Targeted Barriers
(1) Values Affirmation	Two sentences prompting participants to reflect on personal values (with no writing component) [37]	*Please think for a moment about what's most important to you. Whether it's your relationships with family or friends, your religion or spirituality, or your sense of respect and kindness for others, what do you value most?*	Psychological threat of being at-risk for disease, which can lead to rejection of health information
(2) Personalized Risk Information	Personal risk factors for type 2 diabetes (per ADA risk test items) automatically populated in the outreach message, based on participant responses to baseline survey	*In addition to [GDM], our records show you may have these risk factors for diabetes:* • *A family history of diabetes* • *A history of high blood pressure* • *Getting less than 150 minutes of physical activity per week* • *Being 40 or more years of age* • *Carrying excess body weight* • *Being African American, Asian American, Pacific Islander, Latina, or Native American (these groups that face higher risk)*	Low perceived risk for type 2 diabetes
(3) Motivational Interviewing-based	Interactive online module emphasizing personal autonomy for healthcare decision making and prompting participants to consider pros and cons of completing the screening test	*Ultimately, the choice [to complete the screening test] is yours.* • *What is the most important reason you would want to get tested?* • *What is the most important reason you would <u>not</u> want to get-tested?* • *Here's what you've told us so far…* • *Where does that leave you now?*	Ambivalence surrounding behavior change
(4) Action Planning	Interactive online module prompting participants to explicitly plan for completing the screening test and problem solve practical barriers. Example plan is provided, tailored to current pregnancy status (pregnant vs. postpartum)	*If you choose to get tested for diabetes, make a plan for <u>when</u> you'll take the test, <u>how</u> you'll get to the lab, <u>who</u> will support you, and <u>what</u> you can do to remember. Think about how you'll overcome barriers that might get in your way.*	Logistical and practical challenges (e.g., time constraints)

ADA, American Diabetes Association.

participants to reflect on their core personal values (without the typical narrative writing task; Table 3) [37]. This streamlined prompt has been shown in our prior work to amplify interest in diabetes prevention [37].

2.3.2. Component 2: personalized risk information

Personalized messages, i.e., those tailored for individual people based on demographic, behavioral, or theoretical constructs [38], have been shown to elicit higher levels of attention and behavior change relevant to prevention and screening [39-42]. This aligns with the elaboration likelihood model of persuasion [43], which posits that individuals process certain messages with greater "elaboration," or careful attention to message content; this in turn prompts attitude change that is more stable and related to future behavior [41]. Personalized messages may be perceived as more salient, thus increasing persuasiveness and potential for behavior change [38]. Here, participants allocated to receive the Personalized Risk Information component were presented with tailored health information regarding their risk factors for type 2 diabetes, based on the ADA risk test [19]. The message was automatically populated with participants' risk factors derived from ADA risk test items in the baseline survey (e.g., family history of diabetes). Personalized content aimed to ensure personal salience of the message while remaining acceptable to patients and feasible for potential future implementation in a health system setting (in which context, risk factors could be derived from the I rather than survey responses).

2.3.3. Component 3: motivational interviewing (MI)

MI is a patient-centered, yet directive approach that promotes behavior change by addressing ambivalence about behavior change, and offering choices without coercion [44,45]. Widely applied in behavioral medicine and other settings [46,47], MI is hypothesized to improve autonomy support, or the extent to which patients view their provider as offering choices, providing relevant information, and acknowledging their views (per self-determination theory) [48,49]. Participants allocated to this component were presented with a series of interactive prompts to consider the pros and cons of engaging in recommended care, with an emphasis on personal autonomy for healthcare decision making. The component included examples to help participants generate responses to each prompt. Participants were first prompted to identify their most important reasons to complete the screening (pros), and their most important reasons to *not* complete the screening (cons). Next, these were automatically combined to produce a reflection (*"Here's what you've told us so far:* '[response to first prompt].' *On the other hand, you've said* '[response to second prompt]'.*"*). A third open-ended prompt guided participants to formulate a decision (*"Where does that leave you now?"*). Finally, a close-ended item confirmed willingness vs. unwillingness to be screened; those who responded as the latter were presented with a final open-ended prompt to consider what might change their decision (*"I would feel more willing to get tested if…"*).

2.3.4. Component 4: action planning

The logistical challenges of completing the recommended OGTT—a test that requires fasting and over 2 h in a laboratory—are recognized barriers for postpartum patients [22]. Heightened demands from caretaking and work transitions pose significant obstacles [50]. However, action planning and problem-solving approaches developed for chronic disease prevention [51-53] may help patients overcome them. By guiding participants to identify personal barriers, generate solutions, and create an explicit plan to enact the target behavior, action planning may impact self-efficacy (confidence to engage in preventive behaviors despite barriers), an established target in behavioral interventions [54] rooted in social-cognitive theory [55]. Participants allocated to this component were presented with a series of interactive prompts to explicitly plan their screening test and resolve practical barriers. This included four prompts to consider when they could complete the screening; who might support them (e.g., family members); how they would get to their laboratory (planning for transportation); and what they might do to remember (e.g., creating a smartphone reminder). The component included an example plan, tailored to current pregnancy status (pregnant vs. postpartum). For pregnant participants, the component also included a reminder that by planning their upcoming standard postpartum medical visit as a morning appointment, screening could be done on the same day.

2.4. Outcomes

Assessment of participant-reported outcomes occurred immediately after exposure to the intervention, using measures successfully applied in our prior research [37].

The primary outcome was acceptability, assessed using a 12-item measure of persuasiveness (e.g., extent to which the message was perceived as "persuasive," "memorable," and "applicable to my life") with responses on a 5-point scale from *not at all* to *extremely* [40,42]. Mean scores were used to determine overall acceptability, with higher scores indicating greater acceptability. We expected there to be no clinically meaningful difference in acceptability across components.

Participant-reported items to assess feasibility included perceiving the amount of information as *about right* vs. *too much* or *not enough*; and whether participants attended to the message, by assessing how much participants had read (with response options dichotomized as *none/almost none/some* vs. *most/almost all/all*) [37]. Relevant to the MI-based and Action Planning components, we assessed intervention engagement as the proportion of participants who responded to at least one of the interactive prompts; and descriptively examined those responses. Predetermined thresholds for success included $\geq$80% of participants attending to the message (reading *most/almost all/all* of it) and $\geq$ 80% engagement [56].

Outcomes related to feasibility of study procedures included the ability to implement the MOST factorial design using REDCap; achieving the recruitment goal; and achieving racial/ethnic diversity in the study sample, operationalized as approximately 72% from groups other than White (consistent with the distribution of the GDM patient population in KPNC [57]).

2.5. Analysis

Descriptive statistics were conducted to assess participant demographics stratified by intervention component. To test the effect of each component, we used *t*-tests for continuous variables, and chi-square or Fisher's exact tests for categorical variables, to compare mean outcome scores among those exposed vs. not exposed to each component (i.e., collapsing across conditions in which each component was "on" vs. "off"); tests thus focused on main effects, with a significance level of $\alpha = 0.05$. A target sample size of 156 (78 each in the exposed and unexposed groups) was deemed large enough to inform the feasibility of delivering the intervention and to evaluate recruitment success. As a pilot, the study was designed to focus on acceptability and feasibility rather than emulate a fully powered efficacy trial; therefore a power analysis was not relevant here [58]. Modified intent-to-treat analyses included all participants who completed the baseline assessment and were exposed to the intervention. Quantitative analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC, USA). Qualitative responses to open-ended interactive items were examined descriptively to identify the range of themes presented.

3. Results

A total of 608 patients were identified as eligible for the study via EHR and were contacted by email ($n = 605$) or postal letter ($n = 3$); 177 consented to participate by initiating the survey. Of those,162 completed the baseline survey items and received the intervention, comprising the study sample (Fig. 1). This yielded a recruitment rate of 26.6% after the single recruitment contact, and slightly exceeded the

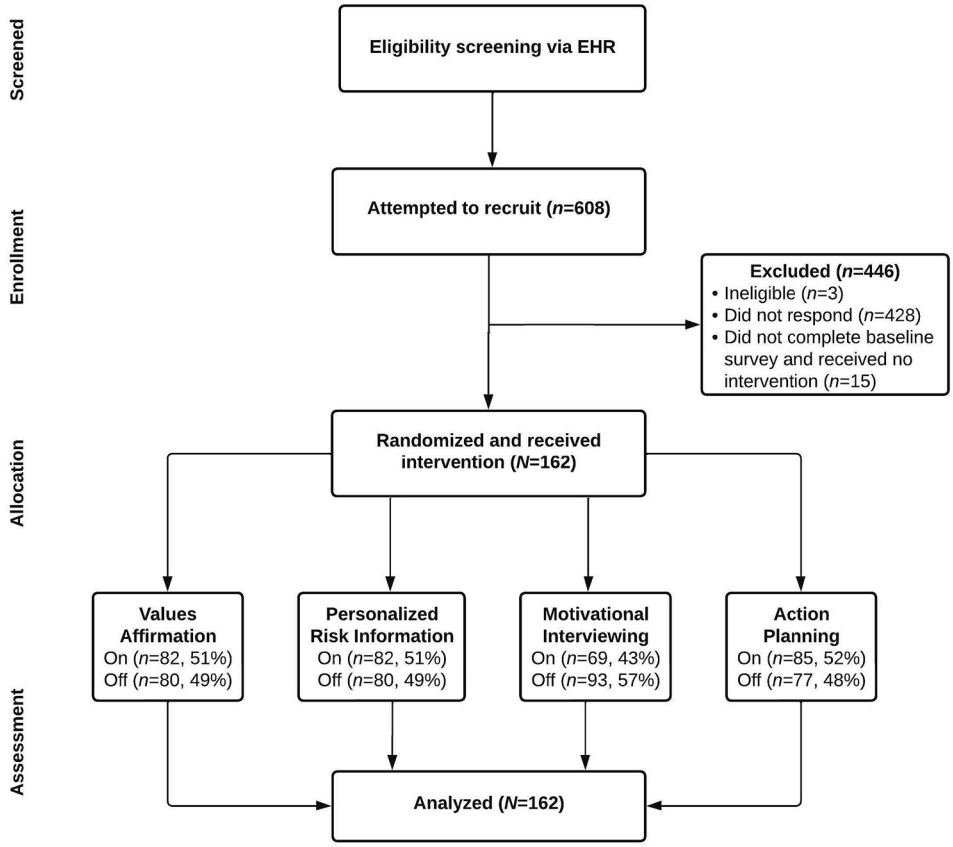

Fig. 1. Participant flow diagram.

recruitment goal of 156 participants. Demographic characteristics, overall and by assignment to each intervention component, are shown in Table 1. In total, 72.2% of participants self-identified with a racial or ethnic minority background and most participants had some college education.

The factorial design yielded 16 experimental conditions. Allocation was successful and relatively even across components, signaling ability to implement the factorial design using REDCap. Acceptability scores averaged 3.9 on a 1–5 scale across components, with higher scores indicating greater acceptability, and did not differ whether each component was "on" vs. "off" (P values $\geq$ .41; Table 4). For participant-reported feasibility outcomes, across components $\geq$89% of participants perceived the amount of information in the outreach message as *about right*; $\geq$ 91% attended to the message. No significant differences emerged for either of these outcomes between conditions in which each component was "on" vs. "off" (P values $\geq$ .27; Table 4).

Regarding engagement, 91.3% (n = 63) completed at least one prompt in the interactive MI-based component and 87.1% (n = 74) completed at least one prompt in the interactive action planning component. In open-ended responses to the MI-based component, important reasons to be screened included being proactive and staying "up to date" on caring for one's health; preventing health problems; staying healthy for oneself and one's family; because of a family history of diabetes; wanting to know if one has diabetes; and for peace of mind.

Table 4
Acceptability and participant-reported feasibility outcomes by intervention component.

	(1) Values Affirmation			(2) Personalized Risk Information			(3) Motivational Interviewing-based			(4) ActionPlanning		
	On	Off	*P* value[c]	On	Off	*P* value[c]	On	Off	*P* value[c]	On	Off	*P* value[c]
Acceptability, Mean (SD) (1–5 scale)[a]	3.9 (0.69)	3.9 (0.67)	0.41	3.9 (0.71)	3.9 (0.65)	0.56	3.9 (0.73)	3.9 (0.65)	0.99	3.9 (0.70)	3.9 (0.66)	0.77
Amount of information, % (n)[b]			0.81			0.46			0.81			0.65
About right	90.1 (73)	91.3 (73)		89.0 (73)	92.4 (73)		91.3 (63)	90.2 (83)		91.7 (77)	89.6 (69)	
Not enough/Too much	9.9 (8)	8.8 (7)		11.0 (9)	7.6 (6)		8.7 (6)	9.8 (9)		8.33 (7)	10.4 (8)	
Attended to message, % (n)			0.79			0.37			1.0			0.27
Most/Almost all/All	92.7 (76)	93.8 (75)		91.5 (75)	95.0 (76)		92.8 (64)	93.6 (87)		95.3 (81)	90.9 (70)	
None/Almost none/Some	7.3 (6)	6.3 (5)		8.5 (7)	5.0 (4)		7.3 (5)	6.5 (6)		4.7 (4)	9.1 (7)	

[a] $n = 151$.
[b] $n = 161$.
[c] Obtained by t test for continuous variables; and χ^2 or Fisher's exact test for categorical variables.

Themes reflecting reasons not to be screened included fear or avoidance of abnormal results; the test being unpleasant, inconvenient, or time consuming; transportation or childcare needs; not feeling the test is necessary; time spent away from one's newborn; fear of judgmental responses from healthcare providers; breastfeeding; feeling unwell after delivery; not wanting "doctors telling me what to do"; and concerns over healthcare costs or lack of insurance. In the action planning component, themes included planning to complete screening on a specific date; on the day of the standard postpartum visit; when work constraints would allow; when "healthier," e.g., after additional postpartum weight loss and healthy eating; and when recommended by one's physician.

4. Discussion and conclusion

4.1. Discussion

Few randomized controlled trials have targeted patient-level influences on the uptake of postpartum diabetes screening as recommended for patients with GDM. The present pilot study examined the acceptability and feasibility of a novel, multicomponent digital health outreach intervention designed to promote screening among diverse patients in a health system setting. Results indicate that each of the four intervention components tested here are acceptable, with average scores of nearly 4 on a 5-point scale and no meaningful differences across components, as expected. Results also indicated high feasibility for each intervention component, as demonstrated by the large proportion of participants across components who perceived the outreach message as conveying an appropriate amount of information. Results met predetermined thresholds for success, including $\geq$80% of participants attending to the outreach message and $\geq$ 80% engaging in the interactive MI-based and Action Planning components.

Themes derived from open-ended responses to the MI-based and Action Planning components reflect the wide variety of barriers and facilitators to engaging in recommended postpartum screening, and echo results from the quantitative survey items assessed at baseline [12]. Aligned with the conceptualization by Michie and colleagues [59], themes observed here broadly reflect patients' capability, opportunity, and motivation to engage in the target behavior of postpartum screening. Interventions to improve rates of screening must be flexible enough to acknowledge and address each of these determinants of the uptake of postpartum care. Of note, some participants indicated interest in lifestyle change and postpartum weight management; outreach that targets screening may also be an opportunity to promote lifestyle programs for diabetes prevention, such as wellness coaching [60] and the National Diabetes Prevention Program [61].

Outcomes related to feasibility of study procedures included successful implementation of the MOST factorial design using REDCap. Although feasible, implementation of numerous REDCap instruments—containing both the survey and the 16 experimental combinations of intervention components, across two strata—was unwieldy. Future study designs might be simplified by delivering intervention components separately from the survey. In addition, slight imbalances in allocation across components could be remedied by modifications to the study design, including a larger sample and additional restricted randomization techniques [62]. Still, the study achieved 103% of the original recruitment goal and a diverse racial/ethnic distribution, with 72% of the sample identifying with a racial or ethnic minority background.

Feasible interventions in clinical settings that encourage routine care following identification of GDM diagnosis are greatly needed. In contrast to very low-intensity interventions such as simple reminders, the current outreach intervention is designed to actively target specific motivational and logistical barriers to screening. Our approach also applies the theories and principles of behavior change interventions to formats that are self-directed, delivered online, and could conceivably be implemented at-scale in health system settings. Adapting these techniques for large-scale delivery via health technology offers strong potential for public health impact. Indeed, motivational interviewing is typically delivered by trained interventionists in individual or group sessions. Similarly, values affirmation typically relies on a writing exercise impractical for large-scale implementation, but streamlined versions may increase scalability [37].

4.2. Strengths and limitations

Strengths of this pilot study include the theory-based intervention, randomized design, and diverse sample, with attention to fidelity as broadly encompassing intervention design, receipt, and enactment. Another strength is the intervention being designed for deployment in an existing integrated health care system. This could facilitate large scale adoption of the intervention in health care settings, if future fully-powered trials demonstrate efficacy. Limitations include the inclusion of patients from a single health system, limiting generalizability. However, Kaiser Permanente is one of the largest health systems in California, whose demographic characteristics reflect those of the regional population [63]. Other limitations include the well-educated sample and inclusion of only English-speaking patients. Future research is needed to test intervention materials across educational levels, across racial and ethnic groups, and among patients with diverse language preferences. The study also lacked a pre-determined threshold for acceptability. Measurement of feasibility for this study may also be viewed as a limitation as this relied on self-reported responses from participants. Future research may consider utilizing REDCap time stamps to measure the length of time spent on each intervention component. Finally, this study was not powered to detect statistically significant differences between groups; as such, the *p*-values provided should be interpreted with caution.

4.3. Innovation

Multi-component outreach interventions hold promise to improve patient engagement in guideline-recommended postpartum diabetes screening. The novel components developed here target unaddressed barriers to patient engagement in guideline-recommended postpartum diabetes screening, including psychological threat, risk perception, ambivalence and competing priorities, and the logistical and practical barriers to screening. The intervention components developed here also demonstrate how theory-based behavior change techniques can be adapted for large-scale use in brief, self-directed, digital formats. For example, values affirmation has been shown to improve a range of academic and other outcomes in adults and youth. Yet with few exceptions, it is rarely tested in clinical populations at high risk for disease; it also typically relies on a writing exercise impractical for large-scale implementation. The streamlined values affirmation tested here is designed to be simple enough (without the writing component) to implement at-scale, while targeting the psychological threat raised by the prospect of a new diagnosis that could discourage preventive care.

4.4. Conclusion

The results from this pilot study suggest that each component of a theory-driven, digital health outreach intervention was acceptable to diverse patients in a health system setting, and feasible to deliver in a brief, online format. Within the MOST framework, results of this Phase 1 Preparation study support the feasibility to conduct a Phase 2 randomized optimization trial to test the effects of each component on rates of postpartum screening. Informed by the present results, this optimization trial is now underway (National Institutes of Health grant R01 DK122087). A definitive trial will still be needed to determine the efficacy of the optimized intervention. Long-term, these systematic studies aim to improve prevention-focused equitable care and maternal health for diverse patient populations.

Funding

This research was supported by a Health Policy and Disparities Research Award from the Kaiser Permanente Northern California Division of Research; and by the National Institute of Diabetes and Digestive and Kidney Diseases (grant numbers R01DK122087, K26DK138246, and P30DK092924). The contents are those of the authors and do not necessarily represent the official views of nor an endorsement by the US Government.

CRediT authorship contribution statement

Susan D. Brown: Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Brittany L. Garcia:** Writing – review & editing, Writing – original draft, Visualization, Formal analysis. **Jenna L. Ritchie:** Writing – review & editing, Resources, Investigation, Data curation. **Ai-Lin Tsai:** Writing – review & editing, Software, Formal analysis, Data curation. **Andrea Millman:** Writing – review & editing, Resources, Project administration. **Mara Greenberg:** Writing – review & editing, Conceptualization. **Charles P. Quesenberry:** Writing – review & editing, Methodology. **Assiamira Ferrara:** Writing – review & editing, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Susan D. Brown reports financial support was provided by the Kaiser Permanente Northern California Division of Research and the National Institute of Diabetes and Digestive and Kidney Diseases.

Acknowledgments

The authors gratefully acknowledge the research participants who contributed to this work.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pecinn.2024.100256.

References

[1] Ferrara A, Hedderson MM, Quesenberry CP, Selby JV. Prevalence of gestational diabetes mellitus detected by the national diabetes data group or the carpenter and coustan plasma glucose thresholds. Diabetes Care 2002;25:1625–30. https://doi.org/10.2337/diacare.25.9.1625.

[2] Jovanovic L, Pettitt DJ. Gestational diabetes mellitus. J Am Med Assoc 2001;286:2516–8. https://doi.org/10.1001/jama.286.20.2516.

[3] Bellamy L, Casas JP, Hingorani AD, Williams D. Type 2 diabetes mellitus after gestational diabetes: a systematic review and meta-analysis. Lancet. 2009;373:1773–9. https://doi.org/10.1016/s0140-6736(09)60731-5.

[4] American Diabetes Association. 13. Management of diabetes in pregnancy: standards of medical care in diabetes-2018. Diabetes Care 2018;41:S137–s143. https://doi.org/10.2337/dc18-S013.

[5] American College of Obstetricians and Gynecologists Committee on Practice Bulletins—Obstetrics. Practice bulletin no. 180: gestational diabetes mellitus. Obstet Gynecol 2017;130:e17–37. https://doi.org/10.1097/aog.0000000000002159.

[6] American Diabetes Association Professional Practice Committee. 15. Management of diabetes in pregnancy: standards of medical care in diabetes—2022. Diabetes Care 2021;45:S232–43. https://doi.org/10.2337/dc22-S015.

[7] Ratner RE, Christophi CA, Metzger BE, Dabelea D, Bennett PH, Pi-Sunyer X, et al. Prevention of diabetes in women with a history of gestational diabetes: effects of metformin and lifestyle interventions. J Clin Endocrinol Metab 2008;93:4774–9. https://doi.org/10.1210/jc.2008-0772.

[8] Brown SD, Hedderson MM, Zhu Y, Tsai AL, Feng J, Quesenberry CP, et al. Uptake of guideline-recommended postpartum diabetes screening among diverse women with gestational diabetes: associations with patient factors in an integrated health system in USA. Brit Med J Open Diabetes Res Care 2022:10. https://doi.org/10.1136/bmjdrc-2021-002726.

[9] Eggleston EM, LeCates RF, Zhang F, Wharam JF, Ross-Degnan D, Oken E. Variation in postpartum glycemic screening in women with a history of gestational diabetes mellitus. Obstet Gynecol 2016;128:159–67. https://doi.org/10.1097/aog.0000000000001467.

[10] Xiang AH, Li BH, Black MH, Sacks DA, Buchanan TA, Jacobsen SJ, et al. Racial and ethnic disparities in diabetes risk after gestational diabetes mellitus. Diabetologia. 2011;54:3016–21. https://doi.org/10.1007/s00125-011-2330-2.

[11] Dennison RA, Fox RA, Ward RJ, Griffin SJ, Usher-Smith JA. Women's views on screening for type 2 diabetes after gestational diabetes: a systematic review, qualitative synthesis and recommendations for increasing uptake. Diabet Med 2020;37:29–43. https://doi.org/10.1111/dme.14081.

[12] Glaser K, Ferrara A, Ritchie JL, Tsai AL, Greenberg M, Quesenberry CP, et al. Perspectives on postpartum diabetes screening among patients with gestational diabetes in an integrated healthcare system. Am J Obstet Gynecol 2022;226. https://doi.org/10.1016/j.ajog.2022.02.010. 857-9.e1.

[13] Clark HD, Graham ID, Karovitch A, Keely EJ. Do postal reminders increase postpartum screening of diabetes mellitus in women with gestational diabetes mellitus? A randomized controlled trial. Am J Obstet Gynecol 2009;200(634):e1–7. https://doi.org/10.1016/j.ajog.2009.01.003.

[14] Van Ryswyk EM, Middleton PF, Hague WM, Crowther CA. Postpartum SMS reminders to women who have experienced gestational diabetes to test for type 2 diabetes: the DIAMIND randomized trial. Diabet Med 2015;32:1368–76. https://doi.org/10.1111/dme.12769.

[15] Zera CA, Bates DW, Stuebe AM, Ecker JL, Seely EW. Diabetes screening reminder for women with prior gestational diabetes: a randomized controlled trial. Obstet Gynecol 2015;126:109–14. https://doi.org/10.1097/aog.0000000000000883.

[16] Ferrara A, Hedderson MM, Ching J, Kim C, Peng T, Crites YM. Referral to telephonic nurse management improves outcomes in women with gestational diabetes. Am J Obstet Gynecol 2012;206(491):e1–5. https://doi.org/10.1016/j.ajog.2012.04.019.

[17] Ferrara A, Schmittdiel JA, Brown SD, Hedderson MM, Feng J, Adams A, et al. Effectiveness of a health system program in delaying the onset of severe diabetes among women with gestational diabetes (GDM). Diabetes. 2016;65:A332.

[18] Collins LM. Optimization of behavioral, biobehavioral, and biomedical interventions: The Multiphase Optimization Strategy (MOST). Springer International Publishing; 2018.

[19] American Diabetes Association. Type 2 diabetes risk test. Available from: http://www.diabetes.org/risk-test; 2023.

[20] Bang H, Edwards AM, Bomback AS, Ballantyne CM, Brillon D, Callahan MA, et al. Development and validation of a patient self-assessment score for diabetes risk. Ann Intern Med 2009;151:775–83. https://doi.org/10.7326/0003-4819-151-11-200912010-00005.

[21] Van Ryswyk E, Middleton P, Shute E, Hague W, Crowther C. Women's views and knowledge regarding healthcare seeking for gestational diabetes in the postpartum period: a systematic review of qualitative/survey studies. Diabetes Res Clin Pract 2015;110:109–22. https://doi.org/10.1016/j.diabres.2015.09.010.

[22] Van Ryswyk EM, Middleton PF, Hague WM, Crowther CA. Women's views on postpartum testing for type 2 diabetes after gestational diabetes: six month follow-up to the DIAMIND randomised controlled trial. Prim Care Diabetes 2016;10:91–102. https://doi.org/10.1016/j.pcd.2015.07.003.

[23] Walker EA, Mertz CK, Kalten MR, Flynn J. Risk perception for developing diabetes: comparative risk judgments of physicians. Diabetes Care 2003;26:2543–8. https://doi.org/10.2337/diacare.26.9.2543.

[24] Keely E, Clark H, Karovitch A, Graham I. Screening for type 2 diabetes following gestational diabetes: family physician and patient perspectives. Can Fam Physician 2010;56:558–63.

[25] Rulison KL, Milroy JJ, Wyrick DL. A randomized iterative approach to optimizing an online substance use intervention for collegiate athletes. Transl Behav Med 2022:12. https://doi.org/10.1093/tbm/ibab119.

[26] Ferrara A, Hedderson MM, Albright CL, Brown SD, Ehrlich SF, Caan BJ, et al. A pragmatic cluster randomized clinical trial of diabetes prevention strategies for women with gestational diabetes: design and rationale of the gestational Diabetes' effects on moms (GEM) study. BMC Pregnancy Childbirth 2014;14:21. https://doi.org/10.1186/1471-2393-14-21.

[27] Cleland C. REDCap for MOST manual. University Park, PA: The Methodology Center, Penn State; 2018.

[28] Brown SD, Grijalva CS, Ferrara A. Leveraging EHRs for patient engagement: perspectives on tailored program outreach. Am J Manag Care 2017;23:e223–30.

[29] Sung M, He J, Zhou Q, Chen Y, Ji JS, Chen H, et al. Using an integrated framework to investigate the facilitators and barriers of health information technology implementation in noncommunicable disease management: systematic review. J Med Internet Res 2022;24:e37338. https://doi.org/10.2196/37338.

[30] Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. J Public Health Dent 2011;71(Suppl. 1):S52–63. https://doi.org/10.1111/j.1752-7325.2011.00233.x.

[31] Borrelli B, Sepinwall D, Ernst D, Bellg AJ, Czajkowski S, Breger R, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. J Consult Clin Psychol 2005;73:852–60. https://doi.org/10.1037/0022-006x.73.5.852.

[32] Cohen GL, Sherman DK. The psychology of change: self-affirmation and social psychological intervention. Annu Rev Psychol 2014;65:333–71. https://doi.org/10.1146/annurev-psych-010213-115137.

[33] McQueen A, Klein WMP. Experimental manipulations of self-affirmation: a systematic review. Self Identity 2006;5:289–354. https://doi.org/10.1080/15298860600805325.

[34] Epton T, Harris PR, Kane R, van Koningsbruggen GM, Sheeran P. The impact of self-affirmation on health-behavior change: a meta-analysis. Health Psychol 2015; 34:187–96. https://doi.org/10.1037/hea0000116.
[35] Ferrer RA, Cohen GL. Reconceptualizing self-affirmation with the trigger and channel framework: lessons from the health domain. Personal Soc Psychol Rev 2019;23:285–304. https://doi.org/10.1177/1088868318797036.
[36] Sweeney AM, Moyer A. Self-affirmation and responses to health messages: a meta-analysis on intentions and behavior. Health Psychol 2015;34:149–59. https://doi.org/10.1037/hea0000110.
[37] Brown SD, Fotuhi O, Grijalva CS, Tsai AL, Quesenberry Jr CP, Ritchie JL, et al. A randomized study of values affirmation to promote interest in diabetes prevention among women with a history of gestational diabetes. Med Care 2019; 57:528–35. https://doi.org/10.1097/mlr.0000000000001133.
[38] Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. Ann Behav Med 1999;21:276–83. https://doi.org/10.1007/bf02895958.
[39] Kessels LT, Ruiter RA, Brug J, Jansma BM. The effects of tailored and threatening nutrition information on message attention. Evidence from an event-related potential study. Appetite 2011;56:32–8. https://doi.org/10.1016/j.appet.2010.11.139.
[40] Kreuter MW, Bull FC, Clark EM, Oswald DL. Understanding how people process health information: a comparison of tailored and nontailored weight-loss materials. Health Psychol 1999;18:487–94. https://doi.org/10.1037//0278-6133.18.5.487.
[41] Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychol Bull 2007;133: 673–93. https://doi.org/10.1037/0033-2909.133.4.673.
[42] Updegraff JA, Sherman DK, Luyster FS, Mann TL. The effects of message quality and congruency on perceptions of tailored health communications. J Exp Soc Psychol 2007;43:249–57. https://doi.org/10.1016/j.jesp.2006.01.007.
[43] Petty RE, Cacioppo J. Communication and persuasion: Central and peripheral routes to attitude change. New York: Springer-Verlag; 1986.
[44] Miller WR, Rollnick S. Motivational interviewing: Preparing people to change addictive behavior. New York: Guilford Press; 1991.
[45] Miller WR, Rollnick S. Motivational interviewing: Preparing people for change. New York: Guilford Press; 2002.
[46] Emmons KM, Rollnick S. Motivational interviewing in health care settings. Opportunities and limitations. Am J Prev Med 2001;20:68–74. https://doi.org/10.1016/s0749-3797(00)00254-3.
[47] Lundahl B, Moleni T, Burke BL, Butters R, Tollefson D, Butler C, et al. Motivational interviewing in medical care settings: a systematic review and meta-analysis of randomized controlled trials. Patient Educ Couns 2013;93:157–68. https://doi.org/10.1016/j.pec.2013.07.012.
[48] Markland D, Ryan RM, Tobin VJ, Rollnick S. Motivational interviewing and self-determination theory. J Soc Clin Psychol 2005;24:811–31. https://doi.org/10.1521/jscp.2005.24.6.811.
[49] Resnicow K, McMaster F. Motivational interviewing: moving from why to how with autonomy support. Int J Behav Nutr Phys Act 2012;9:19. https://doi.org/10.1186/1479-5868-9-19.
[50] Brown SD, Grijalva CS, Ritchie JL, Ferrara A. Motivations to engage in healthy lifestyle behaviors among postpartum women with a history of gestational diabetes (GDM). Diabetes 2017;66:A216.
[51] Kiernan M, Brown SD, Schoffman DE, Lee K, King AC, Taylor CB, et al. Promoting healthy weight with "stability skills first": a randomized trial. J Consult Clin Psychol 2013;81:336–46. https://doi.org/10.1037/a0030544.
[52] Perri MG, Limacher MC, Durning PE, Janicke DM, Lutes LD, Bobroff LB, et al. Extended-care programs for weight management in rural communities: the treatment of obesity in underserved rural settings (TOURS) randomized trial. Arch Intern Med 2008;168:2347–54. https://doi.org/10.1001/archinte.168.21.2347.
[53] Perri MG, Nezu AM, McKelvey WF, Shermer RL, Renjilian DA, Viegener BJ. Relapse prevention training and problem-solving therapy in the long-term management of obesity. J Consult Clin Psychol 2001;69:722–6.
[54] Artinian NT, Fletcher GF, Mozaffarian D, Kris-Etherton P, Van Horn L, Lichtenstein AH, et al. Interventions to promote physical activity and dietary lifestyle changes for cardiovascular risk factor reduction in adults: a scientific statement from the American Heart Association. Circulation. 2010;122:406–41. https://doi.org/10.1161/CIR.0b013e3181e8edf1.
[55] Bandura A. Social foundations of thought and action: A social cognitive theory. Englewoods Cliffs, NJ: Prentice-Hall; 1986.
[56] Kiernan M, Baiocchi MT. Casting new light on statistical power: an illuminating analogy and strategies to avoid underpowered trials. Am J Epidemiol 2022;191: 1500–7. https://doi.org/10.1093/aje/kwac019.
[57] Ferrara A, Hedderson MM, Brown SD, Albright CL, Ehrlich SF, Tsai AL, et al. The comparative effectiveness of diabetes prevention strategies to reduce postpartum weight retention in women with gestational diabetes mellitus: the gestational diabetes' effects on moms (GEM) cluster randomized controlled trial. Diabetes Care 2016;39:65–74. https://doi.org/10.2337/dc15-1254.
[58] Powell LH, Kaufmann PG, Freedland KE. Feasibility and pilot studies. In: Powell LH, Freedland KE, Kaufmann PG, editors. Behavioral clinical trials for chronic diseases: Scientific foundations. Cham: Springer International Publishing; 2021. p. 147–67.
[59] Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011; 6:42. https://doi.org/10.1186/1748-5908-6-42.
[60] Schmittdiel JA, Adams SR, Goler N, Sanna RS, Boccio M, Bellamy DJ, et al. The impact of telephonic wellness coaching on weight loss: a "natural experiments for translation in diabetes (NEXT-D)" study. Obesity (Silver Spring) 2017;25:352–6. https://doi.org/10.1002/oby.21723.
[61] Gruss SM, Nhim K, Gregg E, Bell M, Luman E, Albright A. Public health approaches to type 2 diabetes prevention: the US National Diabetes Prevention Program and beyond. Curr Diab Rep 2019;19:78. https://doi.org/10.1007/s11892-019-1200-z.
[62] Broglio K. Randomization in clinical trials: permuted blocks and stratification. J Am Med Assoc 2018;319:2223–4. https://doi.org/10.1001/jama.2018.6360.
[63] Gordon NP. Similarity of adult Kaiser Permanente members to the adult population in Kaiser Permanente's northern California service area: Comparisons based on the 2017/2018 cycle of the California health interview survey. Oakland, CA: Kaiser Permanente Division of Research; 2020.